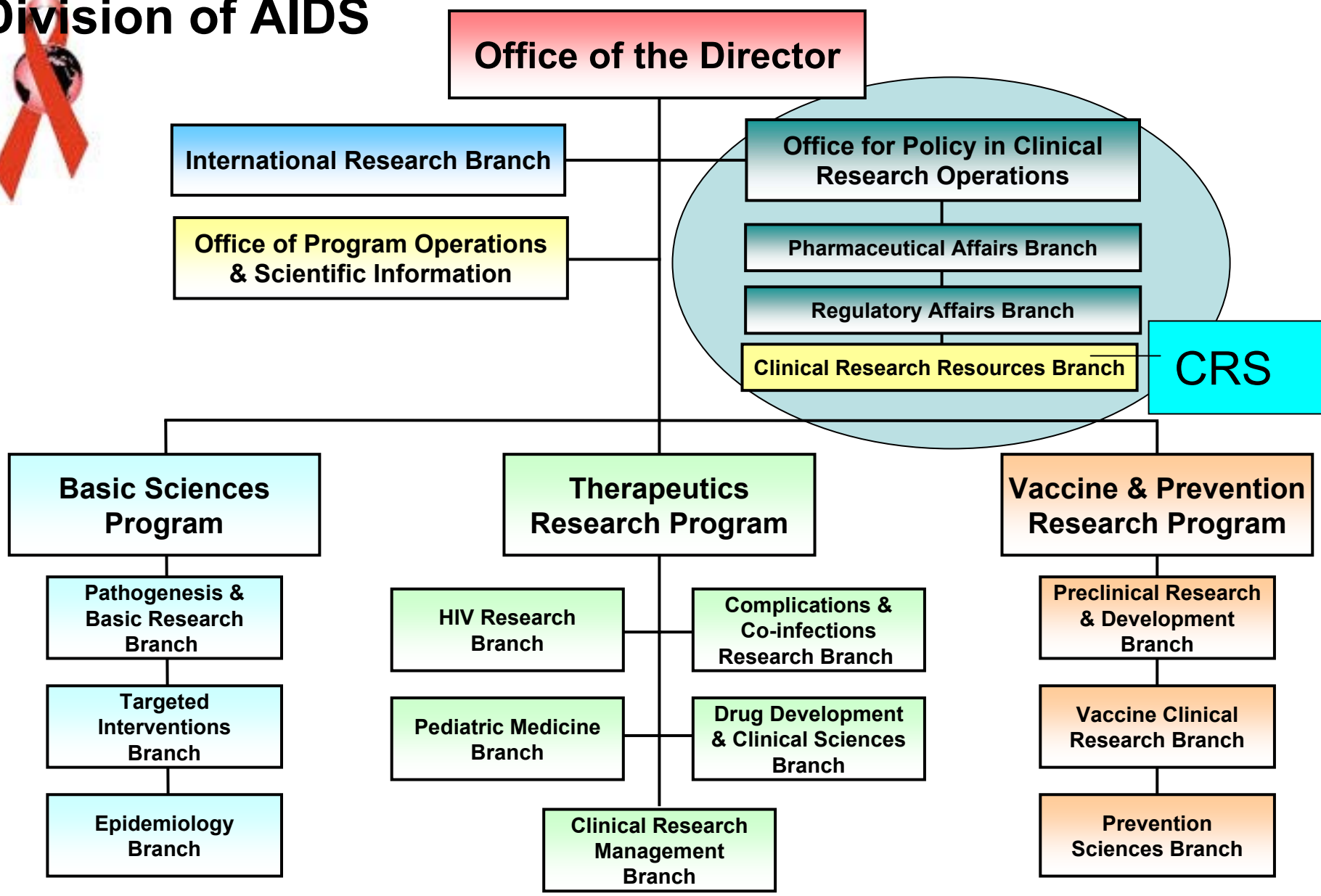# HIV Clinical Research Management Support (CRS) Contract

Pre-Solicitation Briefing
July 26, 2004

Jacquelyn (Jackie) Burns, MPA
Project Officer
Health Scientist Administrator
Office for Policy in Clinical Research Operations
DAIDS

Division of AIDS

Office of the Director

International Research Branch

Office of Program Operations & Scientific Information

Office for Policy in Clinical Research Operations

Pharmaceutical Affairs Branch

Regulatory Affairs Branch

Clinical Research Resources Branch

CRS

Basic Sciences Program

- Pathogenesis & Basic Research Branch
- Targeted Interventions Branch
- Epidemiology Branch

Therapeutics Research Program

- HIV Research Branch
- Complications & Co-infections Research Branch
- Pediatric Medicine Branch
- Drug Development & Clinical Sciences Branch
- Clinical Research Management Branch

Vaccine & Prevention Research Program

- Preclinical Research & Development Branch
- Vaccine Clinical Research Branch
- Prevention Sciences Branch

The mission of DAIDS is to help ensure an end to the HIV/AIDS epidemic by increasing basic knowledge of the pathogenesis and transmission of the human immunodeficiency virus, or HIV, supporting the development of therapies for HIV infection and its complications, and supporting the development of vaccines and other prevention strategies.

July 2004

Current Environment

- Recompetition of networks requires additional support

- Clinical trials portfolio is dynamic and growing

- Ongoing need for additional international infrastructure

- "Unknowns" drive need for flexibility

Over the past year the DAIDS has written this initiative to address dynamic needs. This mechanism will serve as a cornerstone of support for future research
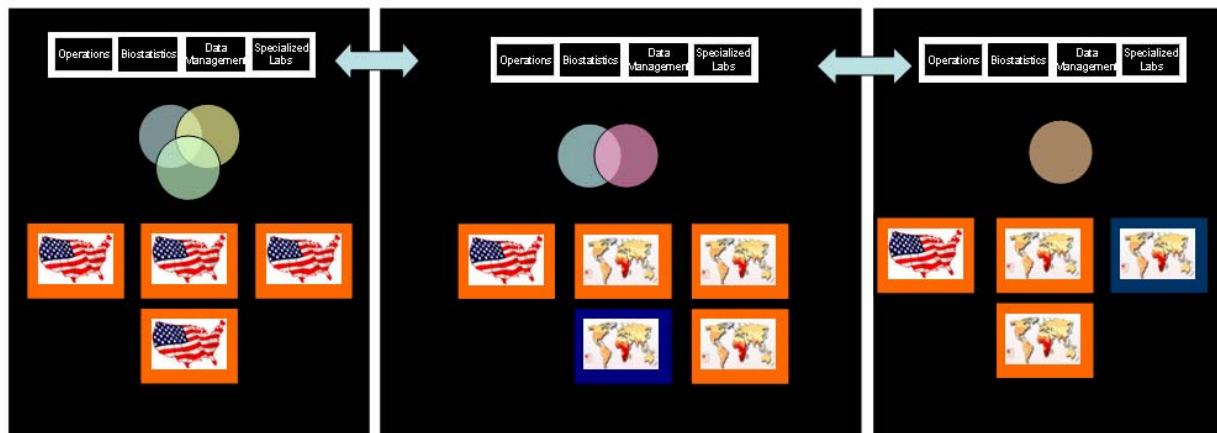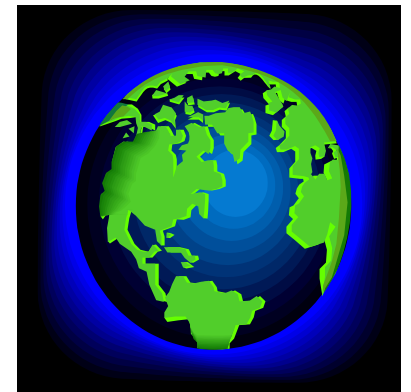
Current activities

The DAIDS has a large, global, dynamic research portfolio consisting of:

- 10+ major programs and/or networks
- 41 countries
- 200+ network and 50+ non-network protocols (or in development) (IND and non-IND)
- 790+ sites
- 1200+ monitoring visits
  - (in 12 months)

What do we want?

## *The best in expert research support*

- A flexible mechanism to support:
  - Inter-network coordination and harmonization
  - Site assessment, planning, management
  - Sustainable presence for infrastructure, long-term development

- Ability to respond to "unknowns" in pharmaceutical development

- Ability to rapidly partner with a multitude of entities

- Ability to fulfill unique needs of institutions/regions
  - Staff recruitment, training, financial mgmt
  - Training
  - Translation

- Facilitate Community Advisory needs and coordination

Design Details
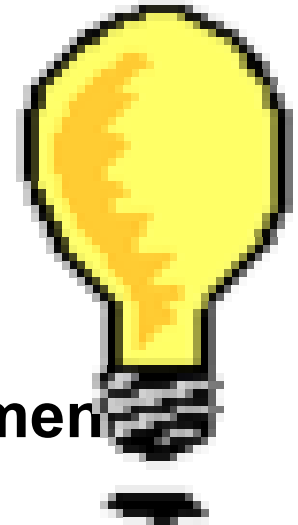
- **Core set of functions**
  - **Research Program Management**
  - **Subcontracts acquisition and management**
  - **Technical oversight of all functions**

- **Non-Core set of functions (the unknowns)**
  - **Accomplished by a sub-concontractor or "in-house"**
  - **Broad spectrum of clinical research management**
    - **Site Establishment and support**
    - **Clinical Trials Management**
    - **Clinical Trials Compliance**

Desired Outcomes

- **Allows DAIDS to respond to and support changing needs and demands of global clinical research portfolio**

- **Facilitates integration of Networks and Investigators as partners**

- **Promotes standardization both internal and external**

- **Networks and users are seamlessly involved-- will approve on work product**

- **Functional and expert international clinical trial infrastructure in all types of settings**

- **Satisfied customers (internal and external)**

Special Feature

- **Case Study….very important**
  - **Your chance to show what sets you apart from the rest**
  - **Show us how you would execute trial…creative….problem-solving**
  - **Address each technical/ops area**
  - **Describe use of internal teams and subcontractors**
  - **Describe management and Communications**

Scenario 1 – All tasks performed by Contractor

TASK: All Investigator-Initiated trials need a one time Quality Assurance audit

1. Core Senior staff meets with PO and defines tasks
2. Core recommends that existing staff within company may do the task.
   - Core determines task can be done 100% within company and confirms this with DAIDS via cost estimate and proposal….approved.
   - Core names a group of Internal QA/Monitor staff who are unknown to each site and have acceptable qualifications
   - Internal team performs QA visits, writes up findings and recommendations and gives to DAIDS.

Scenario 2 - Mixed

Task: Inventory training modules at all sites

1. Core Senior staff meets with PO and defines tasks
2. Core recommends/executes
   - An internal training expert, 2 internal trainers + sub-contractors due to scope of task
   - Proposed subcontractor is approved by DAIDS
   - Internal trainer asks subcontractor to provide personnel to review materials
   - Internal trainer and subcontractor work together
   - Internal trainer QAs deliverables and gives an inventory with recommendations to DAIDS

Scenario 3 – Mixed (Primarily Sub)
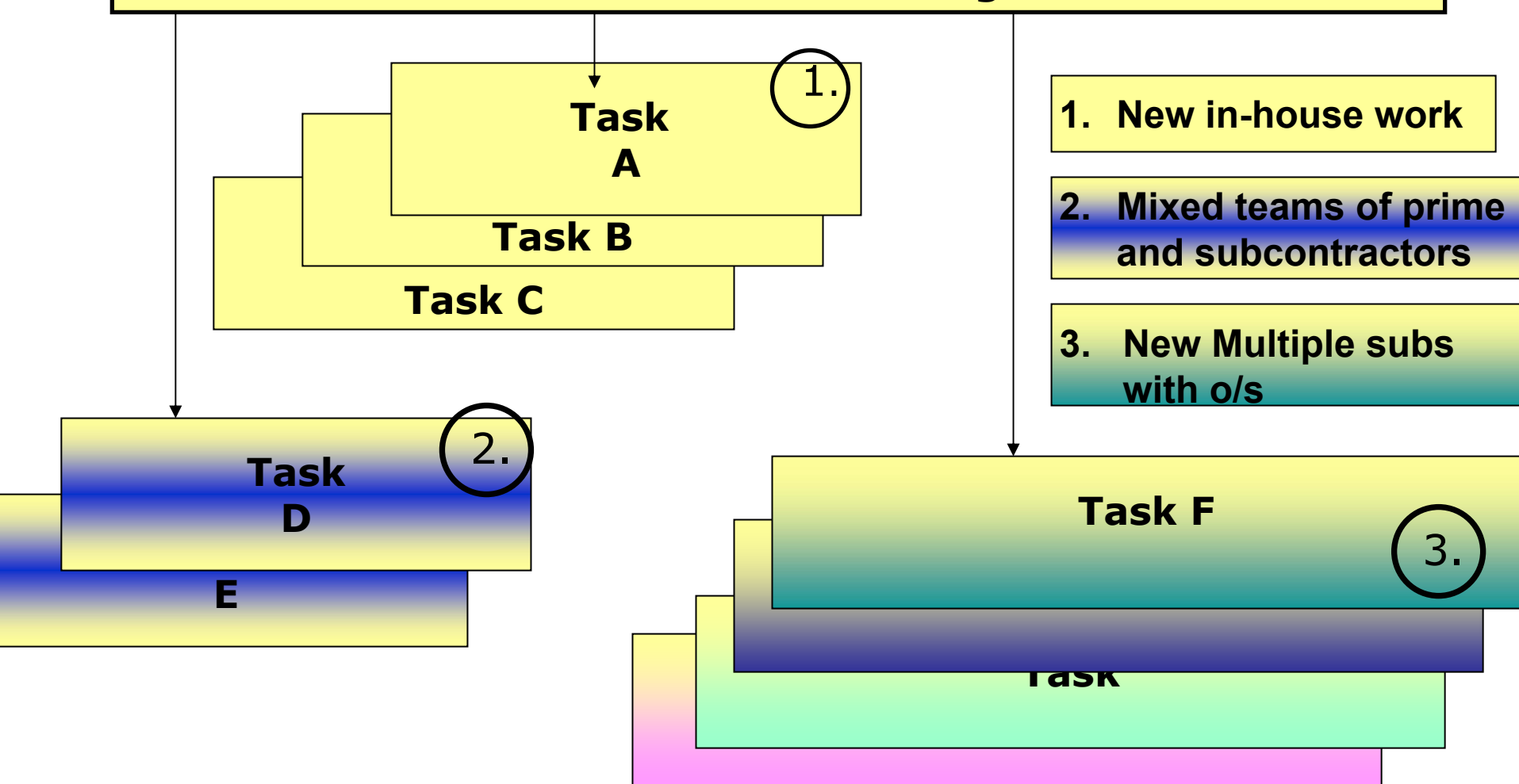
Task: Monitor Phase III trial at 40 sites

1. Core Senior staff meets with PO and defines tasks
2. Core recommends/executes

    - Internal oversight + subcontract monitors
    - Proposed subcontractor is approved by DAIDS
    - Core coordinates with subcontractor and sites
    - Sites are monitored, reports go to DAIDS

CONTRACT - Example of CRS activity

Research Program Management -- Subcontracts Transition

←——— **Technical Oversight** ———→

Task A

Task B

Task C

1.

Task D

E

2.

1. **New in-house work**

2. **Mixed teams of prime and subcontractors**

3. **New Multiple subs with o/s**

Task F

Task

3.

Concluding Remarks

It is our hope and intent that the CRS contract will give us the flexibility to respond rapidly and expertly to meet the demands of the DAIDS international clinical research portfolio.

Thank you for your time and attention to this critical effort..
Your contributions can have a significant, lasting and positive impact on the HIV/AIDS epidemic…

Major programs supported by DAIDS

Vaccines and Prevention:

> HIV Vaccine Trial Network
> HIV Prevention Trials Network
> Integrated Preclinical/Clinical Vaccine Development Program Laboratory
> US Military HIV Research Program

Therapeutics:

> HIV Therapeutics: Targeting Research Gaps
> Acute Infection and Early Disease Research Program
> Adult AIDS Clinical Trials Group
> Pediatric AIDS Clinical Trials Group
> Novel HIV Therapies: Integrated Preclinical/Clinical Program
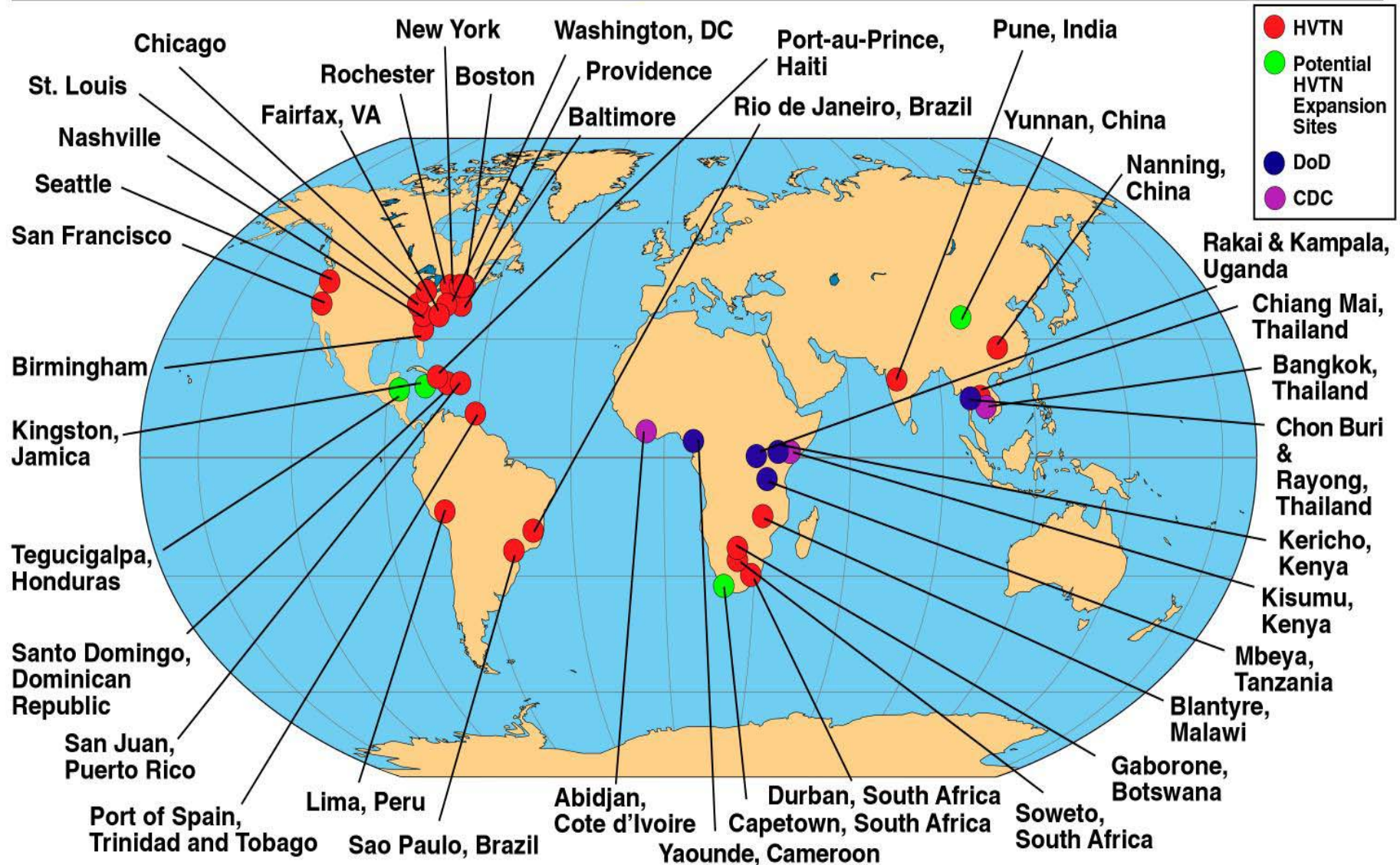
Basic Sciences

> Multi-center AIDS Cohort Study

Across Networks

> Comprehensive International Program for Research on AIDS (CIPRA)
> Investigator Initiated Trials (R01s)

International Evaluation of HIV Vaccines: U.S. Government Sponsored Sites

Other International HIV/AIDS Research Sites